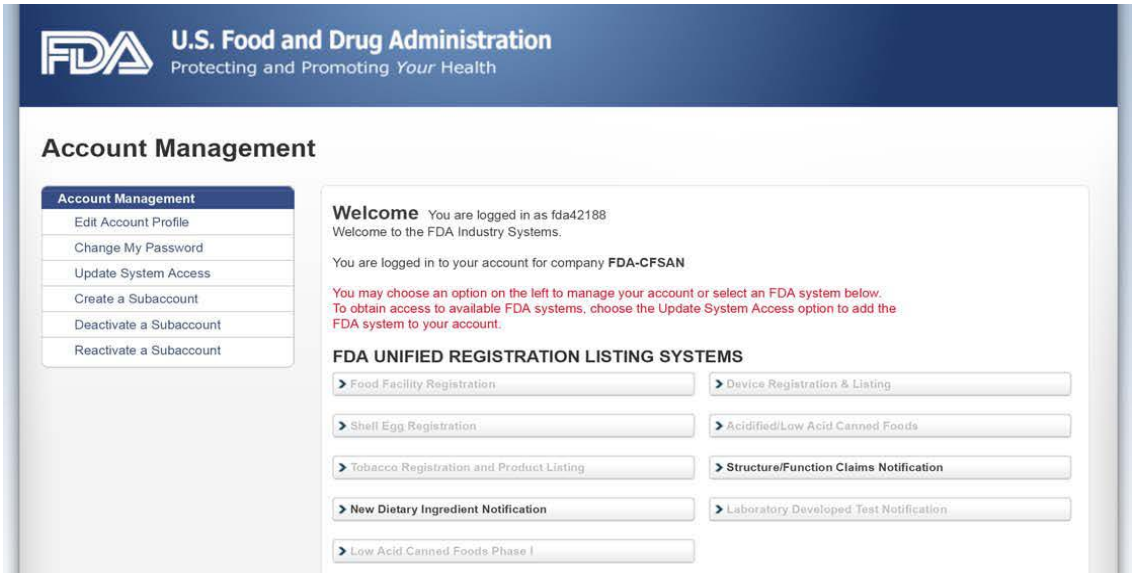
FDA Industry Systems
New Dietary Ingredient Notification
Step-by-Step Instructions
https://www.access.fda.gov/

Enter a New Dietary Ingredient Notification

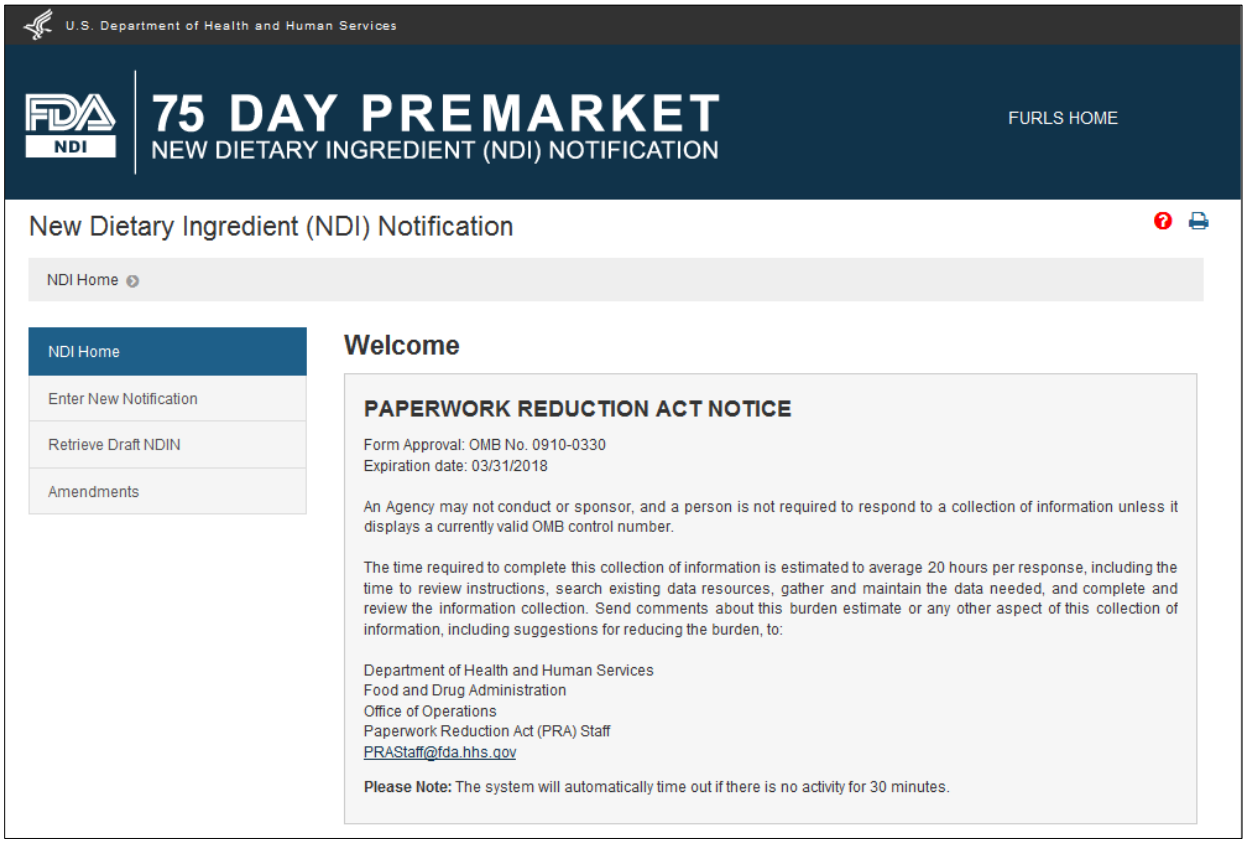
After you log into the FDA Industry Systems page, you will need to select the “New Dietary Ingredient Notification” option from the list of systems available on the FURLS Home Page. See **Figure 1** below.

Figure 1:



Once you have selected “New Dietary Ingredient Notification”, you will navigate to the NDIN main menu. To begin the notification process, select “Enter New Notification” from the list of options on the left. After you have entered an application and saved it as a draft, you may choose to “Retrieve Draft NDIN” from the main menu. See **Figure 2** below.

Figure 2:



STEP 1

Figures 3, 4, 5, 6 and 7 demonstrate the information to be entered into Section 1 of the notification.

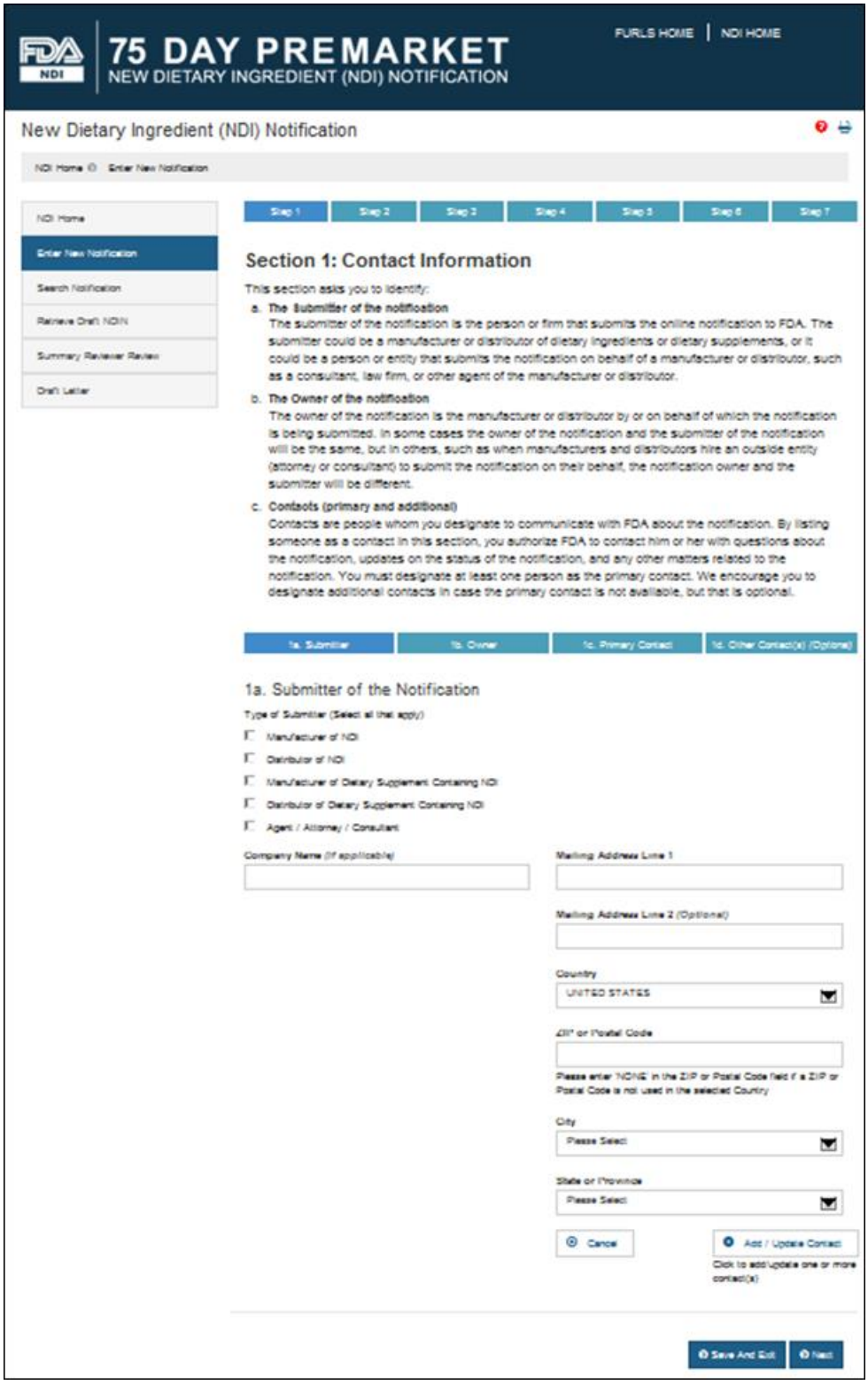
Section 1: Submitter, Notification Owner, and Contact Information

All fields that are not designated as ***OPTIONAL*** must be completed before moving on to the next screen. If all of the required fields are completed with the appropriate information, the notification will be in compliance with the NDIN regulation, 21 CFR 190.6. If these fields are not filled in as required, the primary contact designated in the notification will receive a response letter from FDA indicating that their application is incomplete.

Please enter the following information about the submitter of the notification in Section 1a and then press the "+ Contact/Update Contact" button at the bottom of the screen, see **Figure 3** below.

Field	**Description**
Type of Submitter	Please select the type of firm or person that is submitting the NDI notification. Select **all** that apply. Select "Manufacturer of NDI" if the notification is being submitted by the manufacturer of the NDI. Select "Distributor of NDI" if the notification is being submitted by the distributor of the NDI. Select "Manufacturer of Dietary Supplement Containing NDI" if the notification is being submitted by the manufacturer of a dietary supplement that contains the NDI. Select "Distributor of Dietary Supplement Containing NDI" if the notification is being submitted by the distributor of a dietary supplement that contains the NDI. Select "Agent/ Attorney/ Consultant" if the notification is being submitted by a lawyer, consultant, or other agent on behalf of a manufacturer or distributor of the NDI or of a dietary supplement that contains the NDI.
Company Name	If the submitter is a Company, enter the full name of the company.
Mailing Address Line 1	The street name and number or post office box number for the submitter's mailing address.
Mailing Address Line 2	This line is ***optional***; it can be used to enter a building number, suite number, or other information that doesn't fit on the first line.
Country	The country for the submitter's mailing address. This section defaults to "United States." For foreign addresses, select the appropriate country from the pull-down menu.
Zip Code or Postal Code	The zip code for the submitter's mailing address. For addresses outside the United States, enter the postal code, if any.
City	The city for the submitter's mailing address.
State or Province	The state, province, or territory for the submitter's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.

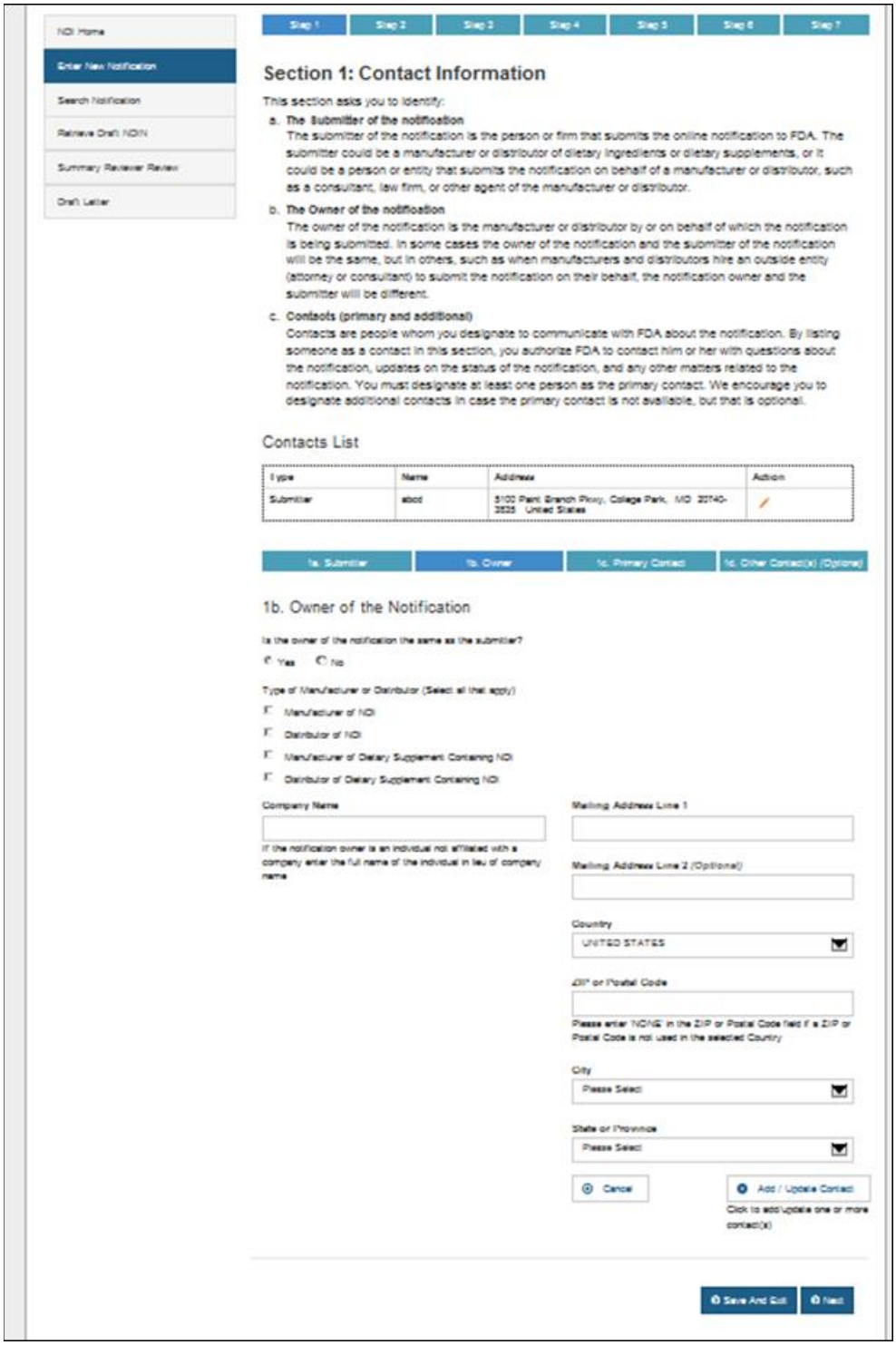
Figure 3:



Enter the following information about the owner of the notification in Section 1b and then press the "+ Add/Update Contact" button at the bottom of the screen, see **Figure 4** below.

Field	**Description**
Is the owner of the notification the same as the submitter?	Answer "Yes" if the owner of the notification is the same as the submitter of the notification identified in Section 1a. Selecting 'Yes' will automatically fill the rest of the fields in Section 1b with the information entered for the submitter of the notification in Section 1a. If you select 'No,' you must fill in the rest of the fields in this Section.
Type of Manufacturer or Distributor	Please select all that apply. Select "Manufacturer of NDI" if the owner of the notification is the manufacturer of the NDI. Select "Distributor of NDI" if the owner of the notification is the distributor of the NDI. Select "Manufacturer of Dietary Supplement Containing NDI" if the owner of the notification is the manufacturer of a dietary supplement that contains the NDI. Select "Distributor of Dietary Supplement Containing NDI" if the owner of the notification is the distributor of a dietary supplement that contains the NDI.
Company Name	If the notification owner is a company, enter the full name of the company. Otherwise, enter the full name of the individual.
Mailing Address Line 1	The street name and number or post office box number for the notification owner's mailing address.
Mailing Address Line 2	This line is *optional*; it can be used to enter a building number, suite number, or other information that doesn't fit on the first line.
Country	The country for the notification owner's mailing address. Defaults to 'United States.' For foreign addresses, select the appropriate country from the pull-down menu.
Zip Code or Postal Code	The zip code for the notification owner's mailing address. For addresses outside the United States, enter the postal code.
City	The city for the notification owner's mailing address.
State or Province	The state, province, or territory for the notification owner's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.

Figure 4:



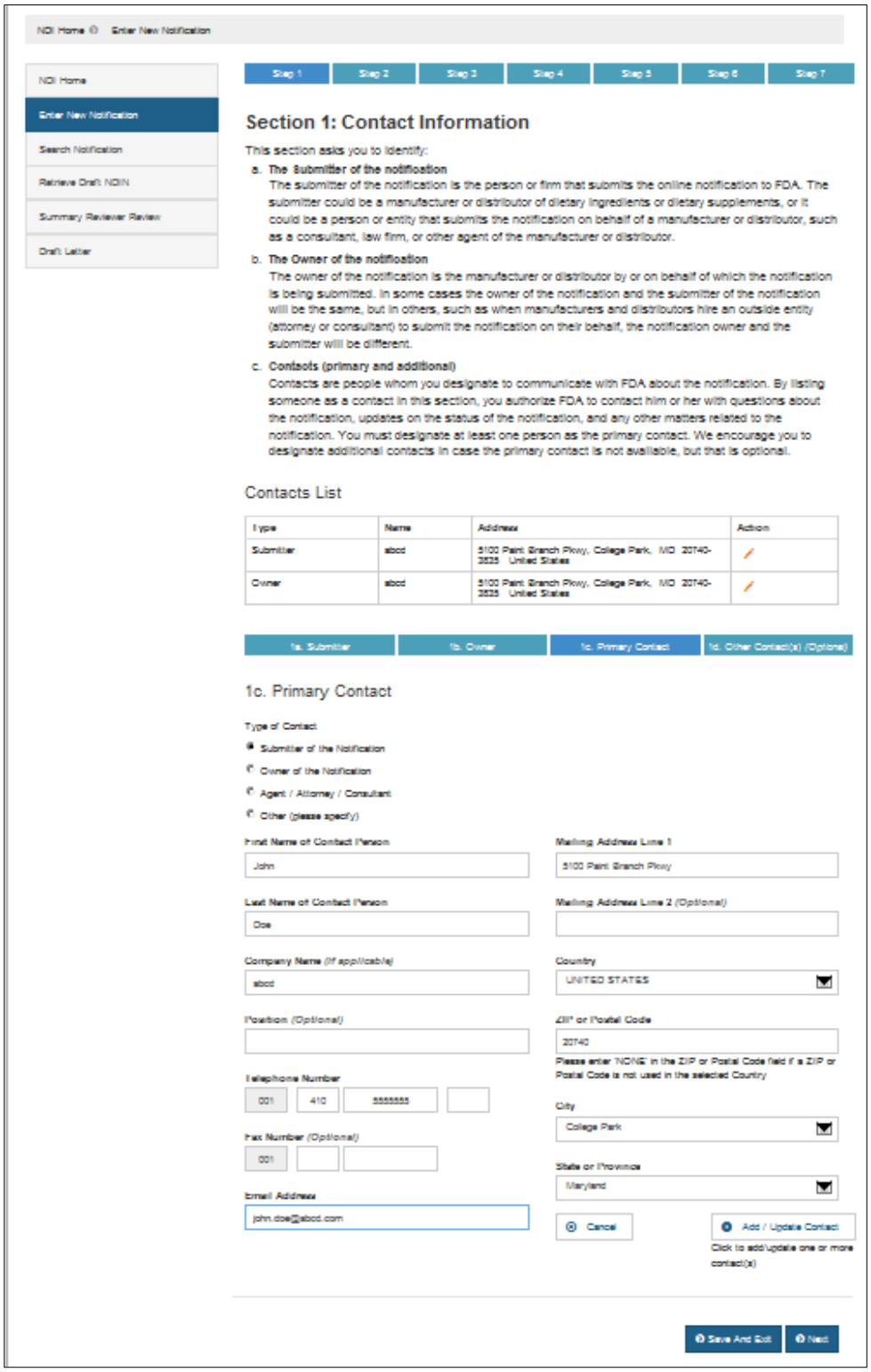
Please specify the primary contact for the notification in Section 1c (see **Figure 5** below). The primary contact is the person designated to communicate (point of contact) with FDA in regard to matters that arise during FDA's review of the notification. The primary contact can be an employee or official of the notification

owner, the notification submitter, or a third party (such as a consultant or attorney). Please provide the following information about the primary contact person in Section 1c and then press the "+ Add/Update Contact" button at the bottom of the screen, see **Figure 5** below.

Field	**Description**
Type of Contact	Select the type of primary contact authorized to communicate with FDA during the notification review. Select "Submitter of the notification" if the contact is an official or employee of the submitter of the NDIN. Selecting this type will automatically fill the company name and address fields in Section 1c with the information provided for the submitter in section 1a. Select "Owner of the notification" if the contact is an official or employee of the owner of the NDIN. Selecting this type will automatically fill the company name and address fields in section 1c with the information provided for the notification owner in section 1b. Select "Agent/Attorney/Consultant" if the contact is an attorney, consultant, or other agent representing the notification owner. If none of the other selections applies, select "Other" to specify an alternative contact type. Describe the contact's relationship to the notification owner or submitter in the field provided.
Name of Contact Person	First and last name of the primary contact person.
Company Name	The name of the primary contact person's company, if any.
Position	Title of the primary contact person.
Mailing Address Line 1	The street name and number or post office box number for the primary contact's mailing address.
Mailing Address Line 2	This line is *optional*; it can be used to enter a building number, suite number, or other information that doesn't fit on the first line.
Country	The country for the primary contact's mailing address. Defaults to 'United States.' For foreign contacts, select the appropriate country from the pull-down menu.
Zip Code (Postal Code)	The zip code for the primary contact's mailing address. For

Field	**Description**
	addresses outside the United States, enter the postal code, if any.
City	The city for the primary contact's mailing address.
State or Province	The state, province, or territory for the primary contact's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
Telephone Number	The telephone number of the primary contact person.
Fax Number	The telephone number of the primary contact person's fax machine.
Email Address	An electronic mail address for the primary contact person.

Figure 5:


NOI Home
Enter New Notification
NOI Home
Enter New Notification
Search Notification
Retrieve Draft NOIN
Summary Reviewer Review
Draft Letter
Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7
Section 1: Contact Information
This section asks you to identify:
a. The Submitter of the notification
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements, or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm, or other agent of the manufacturer or distributor.
b. The Owner of the notification
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and the submitter of the notification will be the same, but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and the submitter will be different.
c. Contacts (primary and additional)
Contacts are people whom you designate to communicate with FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification, and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.
Contacts List
Type
Name
Address
Action
Submitter
abcd
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Owner
abcd
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)
1c. Primary Contact
Type of Contact
Submitter of the Notification
Owner of the Notification
Agent / Attorney / Consultant
Other (please specify)
First Name of Contact Person
John
Last Name of Contact Person
Doe
Company Name (If applicable)
abcd
Position (Optional)
Telephone Number
001
410
Fax Number (Optional)
001
Email Address
john.doe@abcd.com
Mailing Address Line 1
5100 Paint Branch Pkwy
Mailing Address Line 2 (Optional)
Country
UNITED STATES
ZIP* or Postal Code
20740
Please enter 'NONE' in the ZIP or Postal Code field if a ZIP or Postal Code is not used in the selected Country
City
College Park
State or Province
Maryland
Cancel
Add / Update Contact
Click to add/update one or more contact(s)
Save And Exit
Next

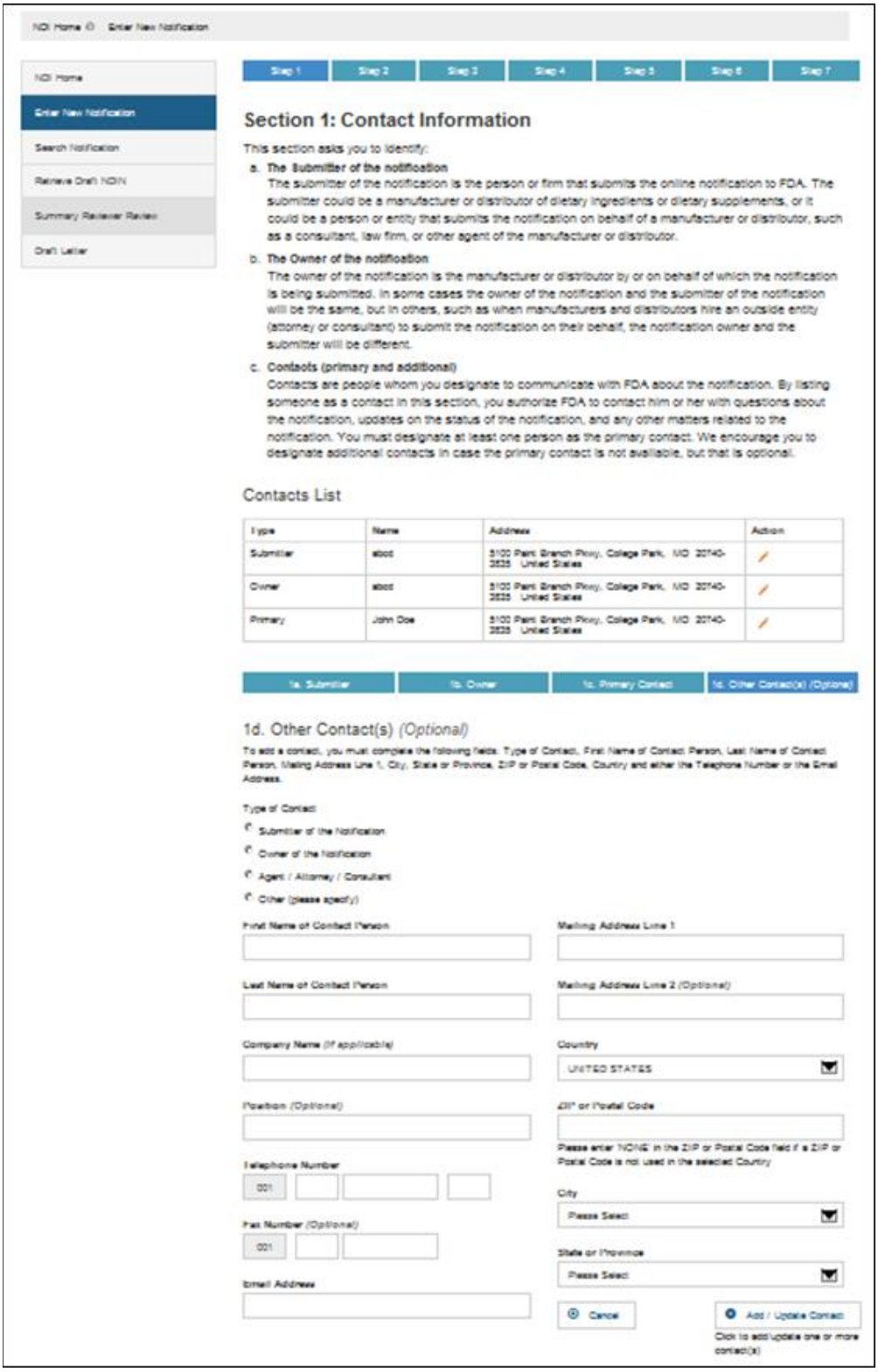
In Section 1d enter the following information for each additional contact that you wish to designate. To add more than one additional contact, enter the contact information and press the button “Add Contact.”

Field	**Dscription**
Type of Contact	Select the type of contact. Select “Submitter of the Notification” if the contact is an official or employee of the submitter of the NDIN. Selecting this type will automatically fill the company name and address fields in Section 1c with the information provided for the submitter in Section 1a. Select “Owner of the Notification” if the contact is an official or employee of the owner of the NDIN. Selecting this type will automatically fill the company name and address fields in Section 1c with the information provided for the notification owner in Section 1b. Select “Agent/Attorney/Consultant” if the contact is an attorney, consultant, or other agent for the notification owner. If none of the other selections applies, select “Other” to specify an alternative contact type. Describe the contact’s relationship to the notification owner or submitter in the field provided.
Name of Contact Person	First and last name of the contact person.
Company Name	The name of the contact person’s company, if applicable.
Position	Title of the contact person.
Mailing Address Line 1	The street name and number or post office box number for the contact’s mailing address.
Mailing Address Line 2	This line is ***optional***; it can be used to enter a building number, suite number, or other information that doesn’t fit on the first line.
Country	The country for the other contact’s mailing address. This section defaults to “United States.” For foreign contacts, select the appropriate country from the pull-down menu.
Zip Code (Postal Code)	The zip code for the contact’s mailing address. For addresses outside the United States, enter the postal code, if any.
City	The city for the contact’s mailing address.

Field	**Dscription**
State or Province	The state, province, or territory for the contact's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
Telephone Number	The telephone number of the contact person.
Fax Number	The telephone number of the contact person's fax machine.
Email Address	An electronic mail address for the contact person.

Other contacts authorized to communicate with FDA during the notification review should be specified in Section 1d (see **Figure 6** below). Additional contacts may also be designated in a separate letter sent as an amendment to the notification at a later date. FDA reviewers will communicate only with authorized contacts.

Figure 6:

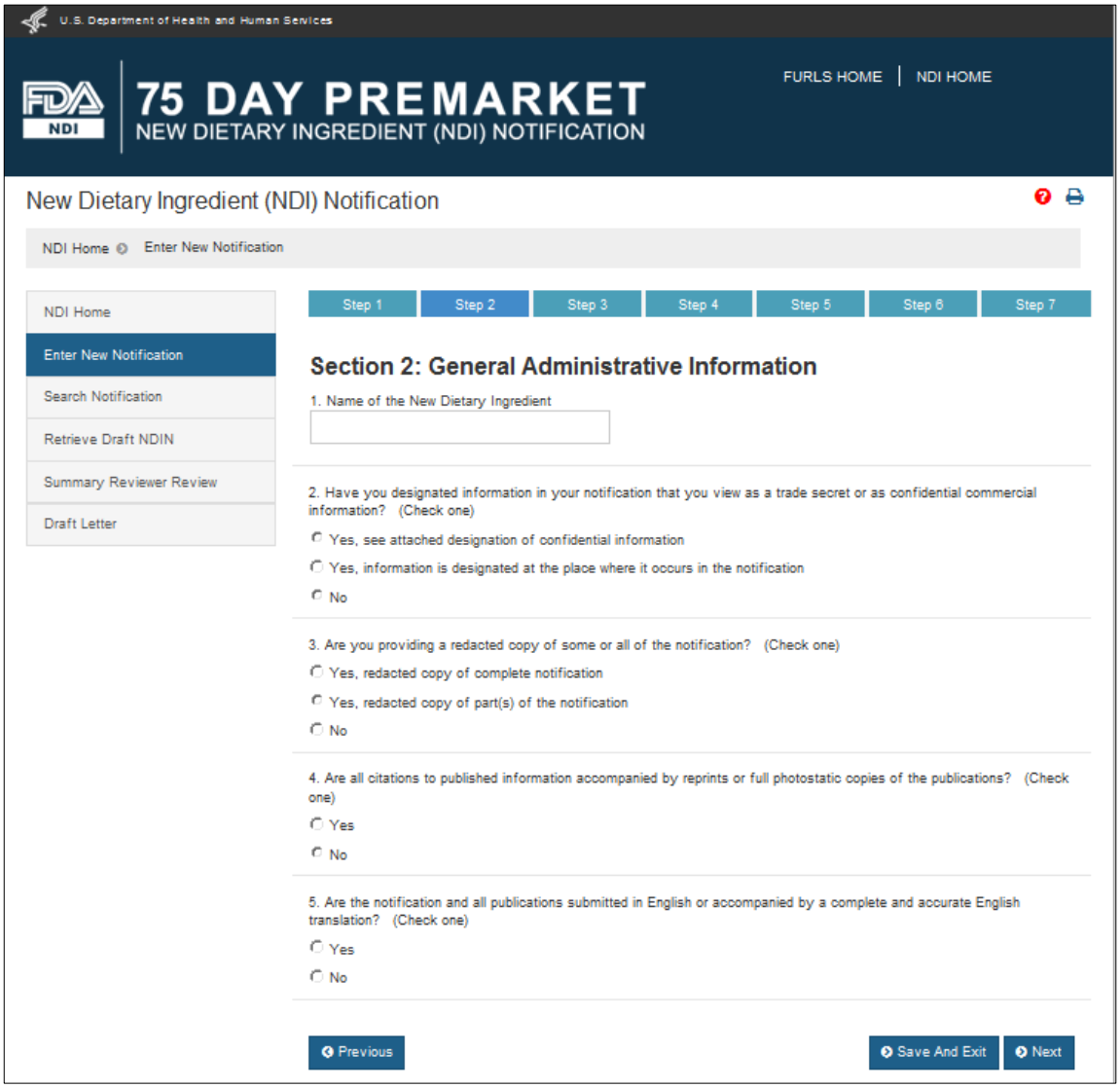

NOI Home
Enter New Notification
Search Notification
Retrieve Draft NOIN
Summary Reviewer Review
Draft Letter
Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7
Section 1: Contact Information
This section asks you to identify:
a. The Submitter of the notification
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements, or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm, or other agent of the manufacturer or distributor.
b. The Owner of the notification
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and the submitter of the notification will be the same, but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and the submitter will be different.
c. Contacts (primary and additional)
Contacts are people whom you designate to communicate with FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification, and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.
Contacts List
Type
Name
Address
Action
Submitter
abcd
5100 Paint Branch Pkwy, College Park, MD 20740-2835 United States
Owner
abcd
5100 Paint Branch Pkwy, College Park, MD 20740-2835 United States
Primary
John Doe
5100 Paint Branch Pkwy, College Park, MD 20740-2835 United States
1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)
1d. Other Contact(s) (Optional)
To add a contact, you must complete the following fields: Type of Contact, First Name of Contact Person, Last Name of Contact Person, Mailing Address Line 1, City, State or Province, ZIP or Postal Code, Country and either the Telephone Number or the Email Address.
Type of Contact
Submitter of the Notification
Owner of the Notification
Agent / Attorney / Consultant
Other (please specify)
First Name of Contact Person
Last Name of Contact Person
Company Name (If applicable)
Position (Optional)
Telephone Number
001
Fax Number (Optional)
001
Email Address
Mailing Address Line 1
Mailing Address Line 2 (Optional)
Country
UNITED STATES
ZIP or Postal Code
Please enter NONE in the ZIP or Postal Code field if a ZIP or Postal Code is not used in the selected Country
City
Please Select
State or Province
Please Select
Cancel
Add / Update Contact
Click to add/update one or more contact(s)

STEP 2

Section 2: General Administrative Information

The form for Section 2 is shown in **Figure 7** below. Section 2 contains general administrative information pertaining to the New Dietary Ingredient Notification.

Figure 7:



Field	**Description**
1. Name of the New Dietary Ingredient	Enter the name of the new dietary ingredient that is the subject of the notification. Please note that for an NDI notification concerning a NDI that is a combination of two or more ingredients, the NDI notification should include safety information for each ingredient as part of the safety information for the NDI notification as a whole.
2. Have you designated information in your notification that you view as a trade secret or confidential commercial information? (Check one)	Select "Yes, see attached designation of confidential information" if there are trade secrets or confidential commercial information in the notification and you are providing an attachment detailing the information you view as confidential. This attachment should be uploaded in Section 5. Select "Yes, information is designated at the place where it occurs in the notification" if you have marked certain material as confidential within the notification. Select "No" if you do not consider any of the information in the notification to be a trade secret or confidential commercial information.
3: Are you providing a redacted copy of some or all of the notification? (Check one)	Select "Yes, redacted copy of complete notification" if you are redacting individual words or sentences throughout the notification. You can send in a redacted copy of the entire notification with these words or sentences blacked out. The redacted copy should be uploaded as an attachment in Section 5. Select "Yes, redacted copy of part(s) of the notification" if you are redacting sections or multiple pages of your notification. You can provide a description of the portions that you want redacted, e.g., "Please redact section 6 from pages 90 – 299 which include data from a 90-day chronic animal study we sponsored." The redacted copy should be uploaded as an attachment in Section 5. Select "No" if you are not including a redacted copy of your notification.
4: Are all citations to published information accompanied by reprints or full photostatic copies of the publication? (Check one)	Select "Yes" if the notification includes reprints or photocopies of all of the publications that were cited. Select "No" if the notification cites publications and does not include reprints or photocopies of all of the publications that were cited. If you select "No" your notification will be incomplete and you will not be able to transmit it to FDA.
5: Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation? (Check one)	Select "Yes" if the entire notification, including any supporting publications, is in English or if the notification includes a complete and accurate English translation of any foreign language materials submitted. Select "No" if any part of the notification, including supporting publications, is being submitted in a foreign language without a complete and accurate English translation. If you select "No," your notification will be incomplete and you will not be able to transmit it to FDA

STEP 3

Section 3: Description of New Dietary Ingredient and Dietary Supplement

Please describe the new dietary ingredient and the dietary supplement that contains the new dietary ingredient by answering the questions in Section 3 (see **Figure 8** below).

Figure 8:

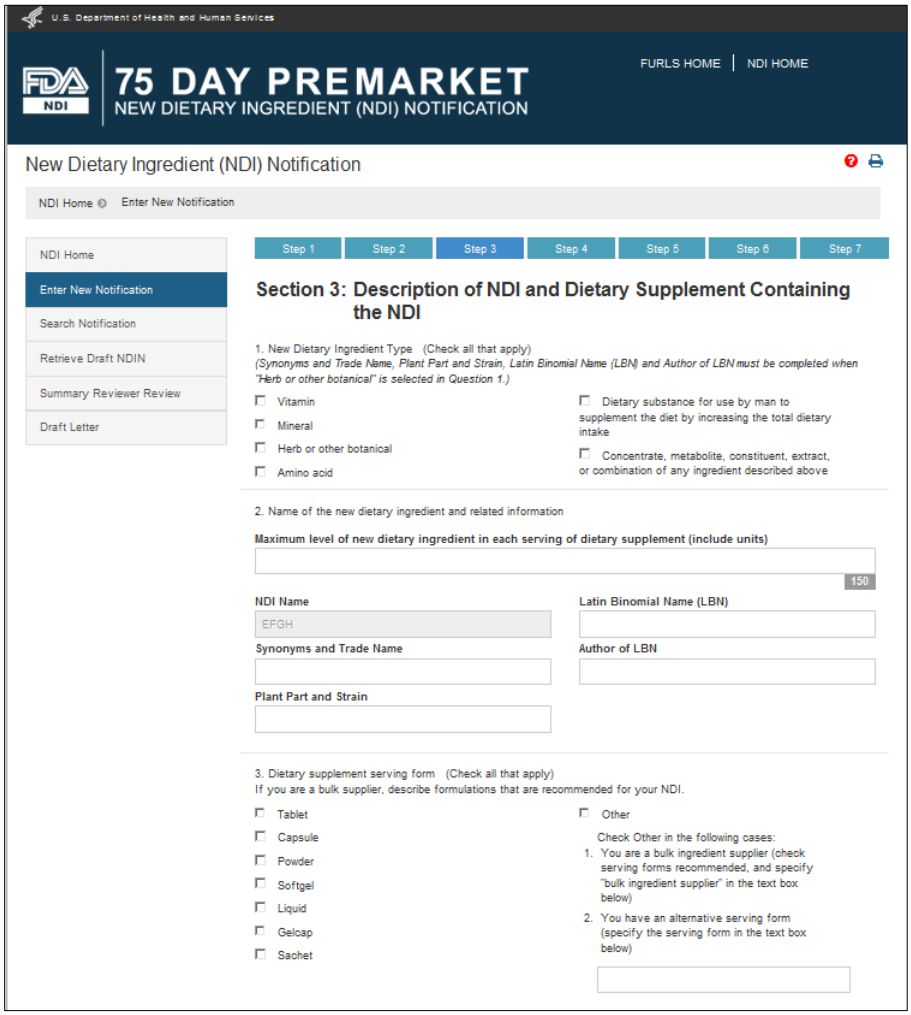
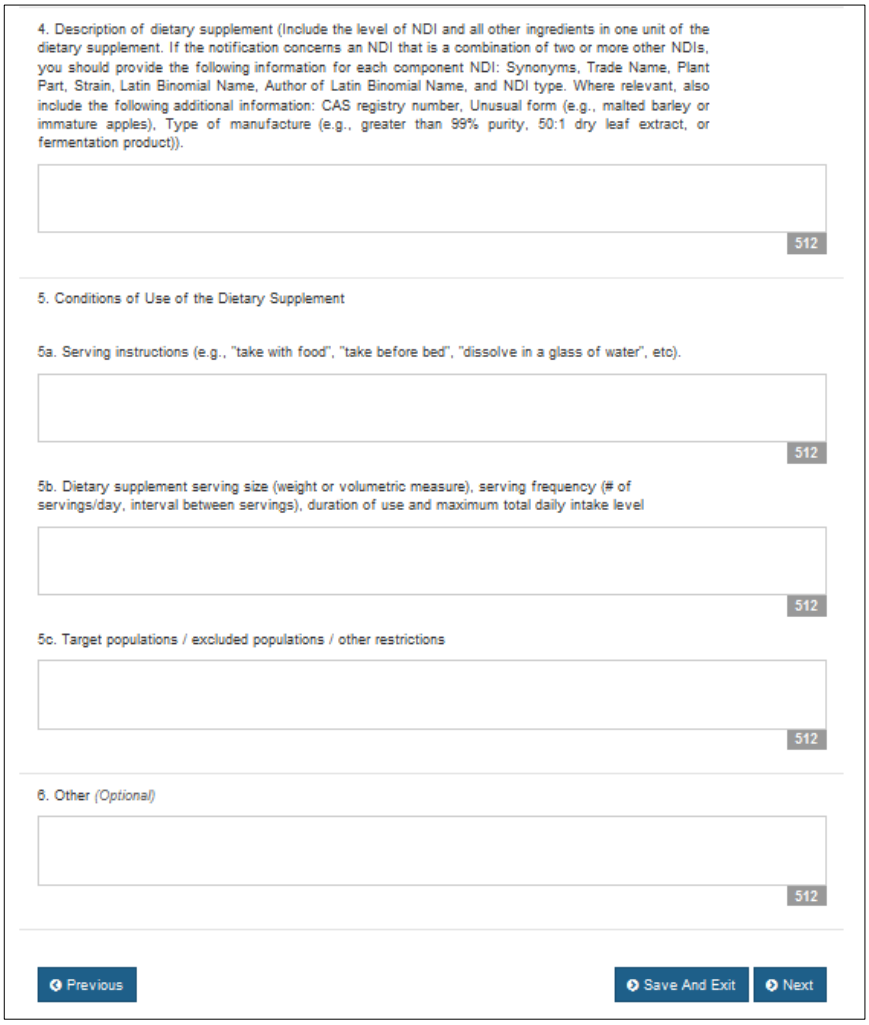


Figure 8 (cont):



Please enter in Section 3 the following information about the new dietary ingredient.

Field	**Description**
1. *New Dietary Ingredient Type (Check all that apply)*	Select the type of dietary ingredient that best describes the new dietary ingredient that you wish to introduce, using the categories provided. If more than one category applies then select all of the applicable categories; e.g., for vanilla extract you would check the "herb or other botanical, "dietary substance," and "concentrate, metabolite, constituent, extract, or combination" boxes.
2: *New dietary ingredient name and related information*	Enter the maximum level of the NDI (including units of measurement) in a serving of the dietary supplement, if your notification applies to a specific dietary supplement. If you are a bulk supplier or if your notification is intended to cover dietary supplements at a range of doses, enter the maximum level of the NDI (including units of measurement) per serving that you have concluded will reasonably be expected to be safe under the conditions of use described in the notification. The NDI name you entered in Section 2 will be filled in for you in the first field below the maximum serving level. Next, list the trade name of the NDI and any synonyms for the NDI (other names under which the NDI is known) that should be used to search the scientific literature about the safety of the NDI. For botanical and microbial NDIs, enter the following additional pieces of information: • The plant part and plant strain from which the NDI is taken. (For microbial NDIs, enter the microbial strain.) • The Latin binomial name. • The author of the Latin binomial name (if applicable).
3: *Dietary supplement serving form (Check all that apply)*	Select the form of the dietary supplement that contains the NDI. If the NDI will be an ingredient of dietary supplements in more than one form, select all of the forms that apply. If the form of your dietary supplement is not listed, select "Other" and describe the form in the text box provided. If you are a bulk ingredient supplier, select "Other", enter "Bulk Ingredient Supplier" in the text box, and select the forms that you recommend. If the serving form you recommend is not listed, describe the form in the text box provided after "Bulk Ingredient Supplier."
4: *Description of dietary supplement (Include level of the NDI and all other ingredients in one unit of the dietary supplement)*	List the names and levels of all of the ingredients in each dietary supplement that contains the new dietary ingredient. Provide the level per unit (i.e., capsule, tablet, etc.) of the dietary supplement, not per serving of the dietary supplement. The level should correspond to the level in a specified serving form in Question 3. You should list both dietary ingredients and other ingredients for each supplement. If the notification concerns a NDI that is a combination of two or more

Field	**Description**
	other ingredients, you should provide the following information for each component of the NDI: Synonyms, Trade Name, and NDI type (using categories from Question 1). Where relevant, you should also include the following additional information for each component NDI: Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., >99% purity, 50:1 dry leaf extract, or fermentation product). If you are a bulk ingredient supplier, provide the requested information about NDI level, other ingredients, form, and type of manufacture based on the conditions of use that you recommend for your NDI and for which you have a reasonable expectation of safety based on history of use or other evidence. If the notification is intended to cover more than one dietary supplement that contains the NDI, enter the description of the first dietary supplement here, and enter the descriptions of the remaining dietary supplements in the safety information attachment you will upload in Section 4.
5: *Conditions of Use of the Dietary Supplement*	Provide information detailing the conditions of use for each dietary supplement that contains the NDI. If you are a bulk ingredient supplier, provide the conditions of use you recommend for dietary supplements that contain the NDI. If the notification is intended to cover more than one dietary supplement that contains the NDI, enter the conditions of use for the first dietary supplement here, and enter the conditions of use for the remaining dietary supplements in the safety information attachment you will upload in Section 4.
5a: *Serving Instructions (e.g., "take with food," "take before bed," "dissolve in a glass of water," etc.)*	Provide information on the serving instructions (directions for use) for each dietary supplement that contains the NDI.
5b: *Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level*	For each dietary supplement that contains the NDI, provide information on the dietary supplement serving size (weight or volumetric measure of one serving of the dietary supplement), serving frequency (number of servings per day, length of time between servings), duration of use, and maximum daily intake level (weight or volumetric measure) of the dietary supplement when taken that are represented in its labeling.
5c: *Target populations/ excluded populations/other restrictions*	For each dietary supplement that contains the NDI, provide information on the population groups for which the product is intended and on any population groups that should not take the product. For example, you may want to state that the dietary supplement should not be taken by pregnant and lactating women or by individuals with certain medical conditions: (e.g., diabetics or individuals unable to metabolize phenylalanine.) Also provide information on any other use restrictions

Field	**Description**
	that may apply. For example, if the intake of the NDI or one of the other dietary ingredients in the supplement needs to be limited for safety reasons, you may want to state that the dietary supplement should not be taken in combination with other dietary supplements that contain the same dietary ingredient.
6: *Other*	Please provide any additional information describing the NDI and the dietary supplement(s) that contains the NDI. This field can also be used as additional space to enter information in response to the questions in this section.

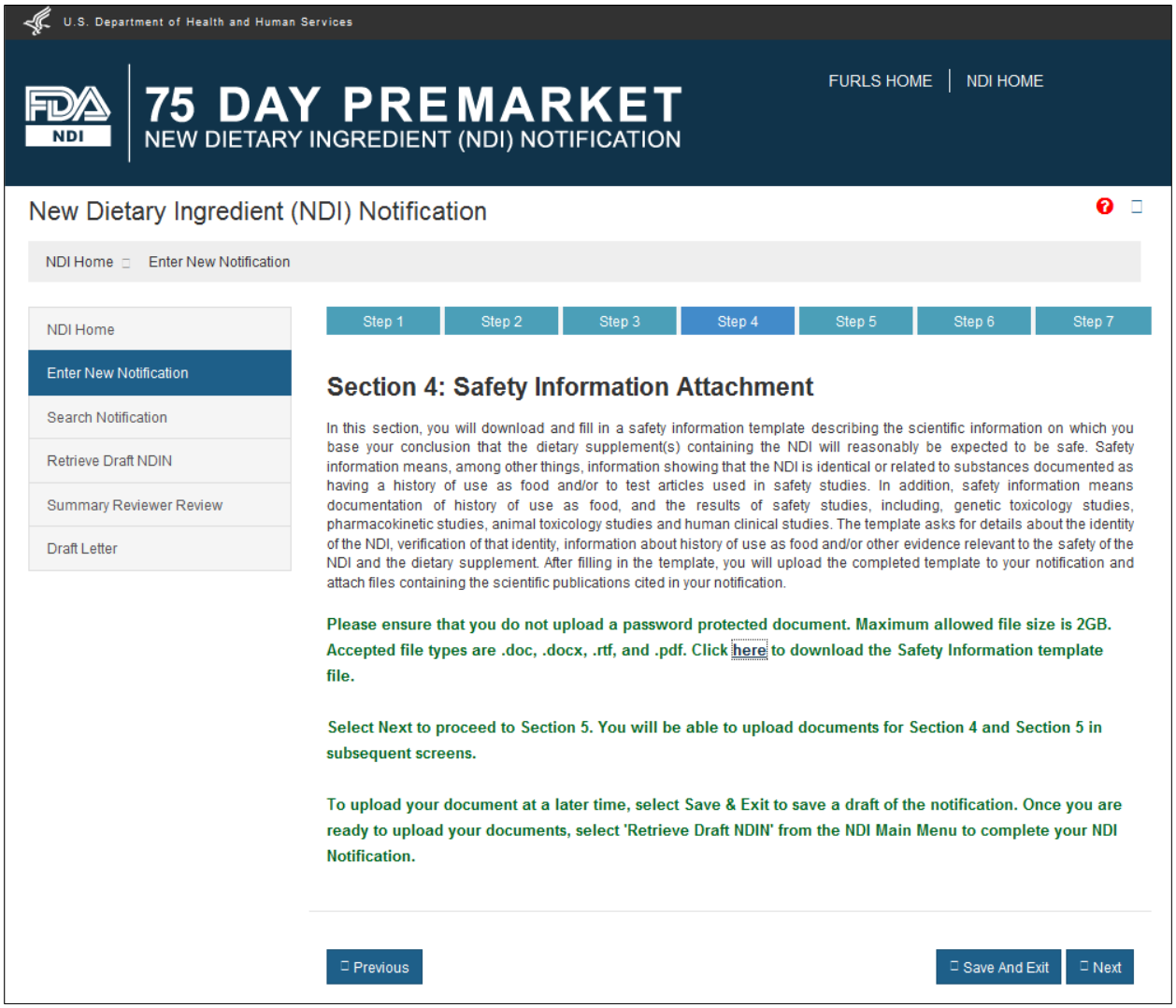
STEP 4

This section must be completed in order to proceed to the next screen.

Section 4: Safety Information Attachment (see **Figure 9** below**)**

In this section, you will download and complete a safety information template that describes the scientific information on which you base your conclusion that the dietary supplement(s) that contains the NDI will reasonably be expected to be safe. Safety information includes, among other things, information demonstrating that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means providing a thorough documentation of the history of use as food, and the results of safety studies, including genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about its history of use as food, and/or other evidence relevant to the safety of the NDI and the dietary supplement. The template also asks for reprints or photostatic copies of all cited studies. After filling in the template, you must upload the completed safety information template file and files that contain the scientific publications cited in your notification.

Figure 9:



To download the template file that is provided for entering your safety information, click on the blue link in the sentence “Click **here** to download the Safety information template file.” After you have downloaded the template file, fill out the all of sections in the template with the requested information pertaining to your NDI and the dietary supplement(s) that contains the NDI, attach any published and unpublished articles cited within the notification, and save the completed template to your computer in one of the supported file formats (doc, docx, rtf, or pdf). You may find it advantageous to combine the completed safety information template file and the files that contain cited studies in one file, and upload this single file in the section called “Safety Information Attachment.” Alternatively, you may attach the files that contain cited studies separately by combining these files into a single file for each of the following: identity, history of use and other evidence of safety, and attach these three files in the

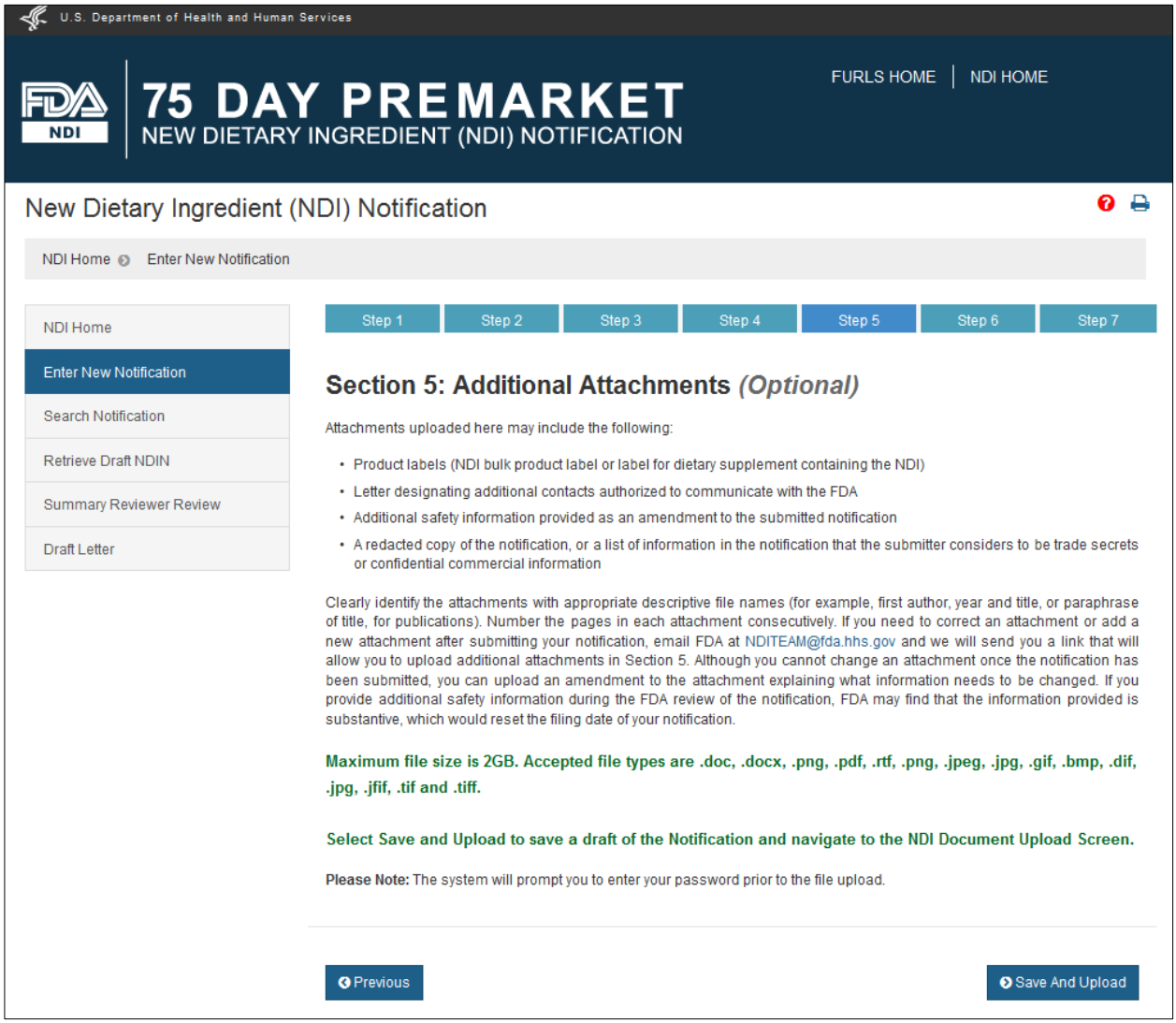
Optional Section called “Additional Attachments” (See Section 5). You will be prompted to upload the attachments that are pertinent to Sections 4 and 5 in subsequent screens.

STEP 5

Section 5: Additional Attachments (*This is an optional section*)

Any additional attachments that might be included with the NDI notification are explained in Section 5 (see **Figure 10** below). You should clearly identify the attachments with appropriately descriptive file names (for example: first author, year, and title or paraphrase of title for publications). The page numbers in each attachment should be numbered consecutively.

Figure 10.

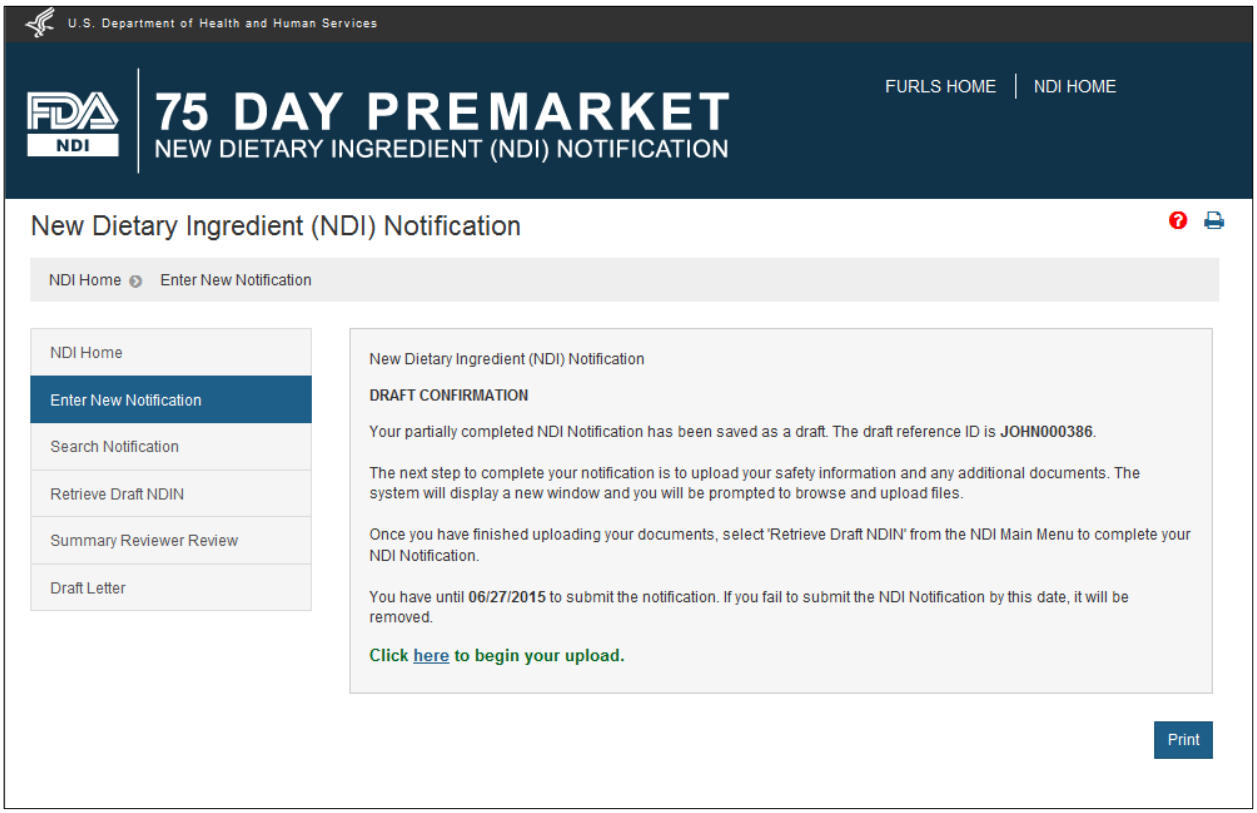


Attachments that are uploaded in this section may include the following: Product labels

(label for dietary supplements that contain the NDI or NDI bulk label), letter designating additional contacts authorized to communicate with the FDA during the notification review, additional safety information provided as an amendment to the notification, redacted copy of the notification, or list of information you believe is trade secret or confidential commercial information for FDA's consideration. If you upload the labeling for the dietary supplement that contains the NDI it will facilitate FDA's evaluate regarding the conditions of use that you recommended or suggested. If you are the manufacturer or distributor of the NDI and do not have access to labeling for the dietary supplement(s) in which the NDI will be used, please upload the labeling of the bulk NDI. Buttons are provided for adding, editing and deleting attachments. If you need to correct an attachment or add a new attachment after the notification has been submitted, contact FDA at NDITEAM@fda.hhs.gov and we will set the status of your application such that, for 5 days, the system will allow you to upload additional attachments. Although you cannot change an attachment once your notification has been submitted to the FDA, you can upload an amendment that explains what information needs to be changed.

To save a draft of the notification in preparation for uploading your attachments, press the button "Save and Upload," located on the far right on the bottom of the screen. The next screen is the confirmation screen, which provides you with a draft reference ID and a deadline to submit the draft notification (see **Figure 11** below). Click on the blue link in the sentence "Click **here** to begin your upload" at the bottom of the screen, and you will be directed to the screen "NDI Document Upload" to begin selecting files to upload.

Figure 11.



Submitting an NDIN Electronically and NDI Document Upload:

Figures 12, 13, and 14 illustrate the screens you will see as you navigate away from the electronic submission portal to the "NDI Document Upload" section. The first screen for the "NDI Document Upload" includes a description of the "Safety Information Attachment" section of the notification at the top half of the screen (see **Figure 12** below) and the description of Section 5 of the electronic submission portal (Additional Attachments) at the bottom half of the screen (see **Figure 13** below). Under the "Safety Information Attachment" heading, you will see a box captioned "Add Attachment." Click on the "Browse" button in the box to locate the safety information file with the completed template on your computer and select it, and then click "Upload". Then scroll down to the "Additional Attachments" heading and locate the box captioned "Add Attachment(s)" below it. Click on the "Browse" button in the box to locate any additional attachments (e.g., publications you are submitting in support of your notification) on your computer, select them, and then click "Upload". Click the Submit button at the bottom of the screen to attach the uploaded documents to your draft notification. A confirmation that the attachments have been uploaded will appear and explain the next step that is required to complete the notification. After you have uploaded the attachments to your notification, click on the blue link in the sentence "Click **here** to go to FURLS Home" at the bottom of the screen, and you will be directed to the screen "FURLS Home" to retrieve the draft notification from the NDI Home Main Menu and continue with the electronic submission at Step 6. In Step 6, you will be given the opportunity to review the information you have entered and make changes before submitting the notification to FDA.

Figure 12:

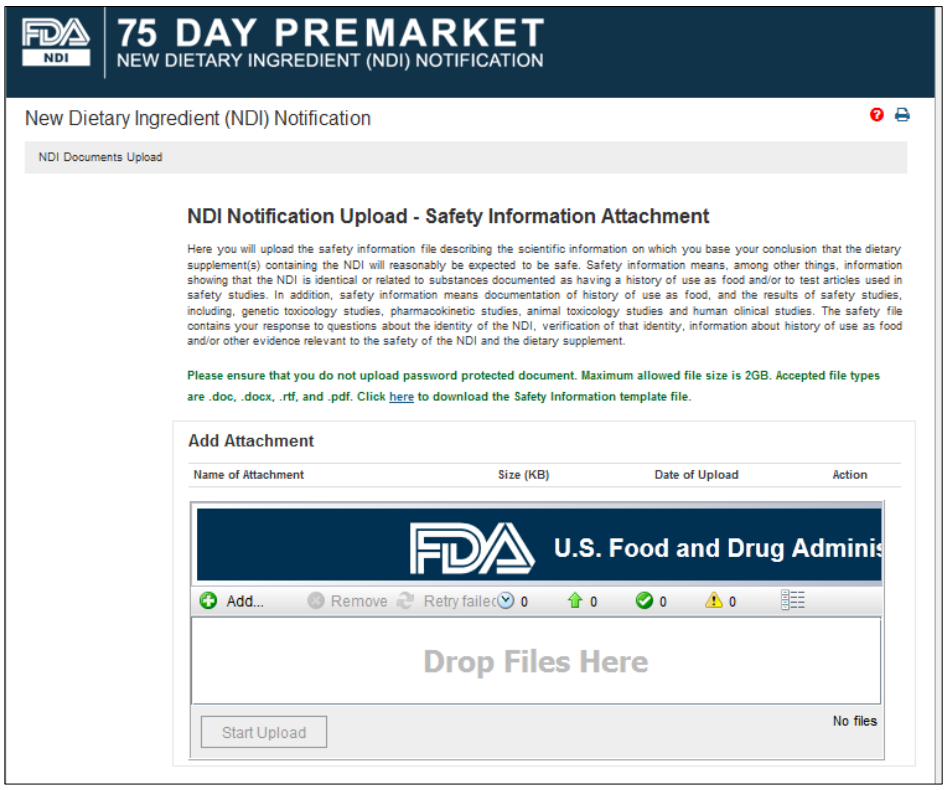
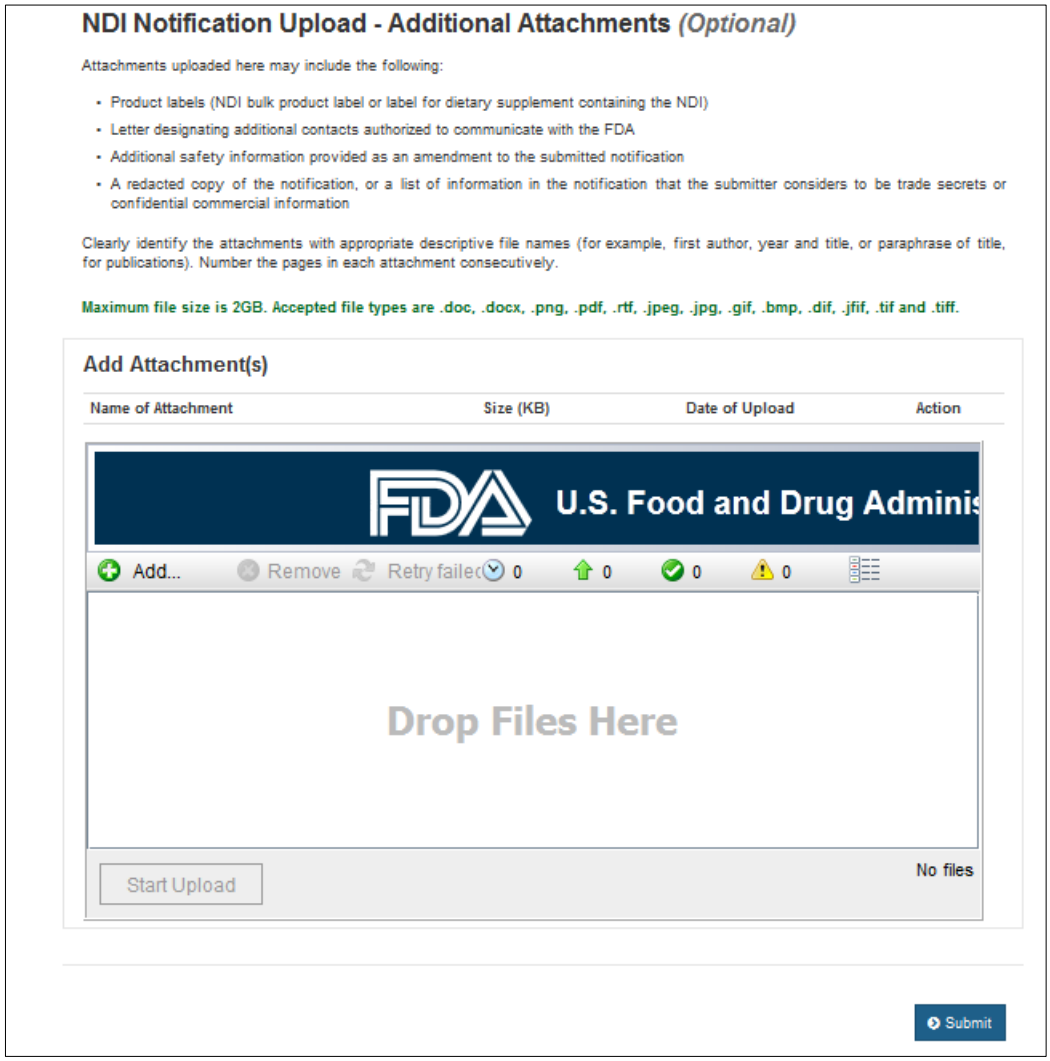
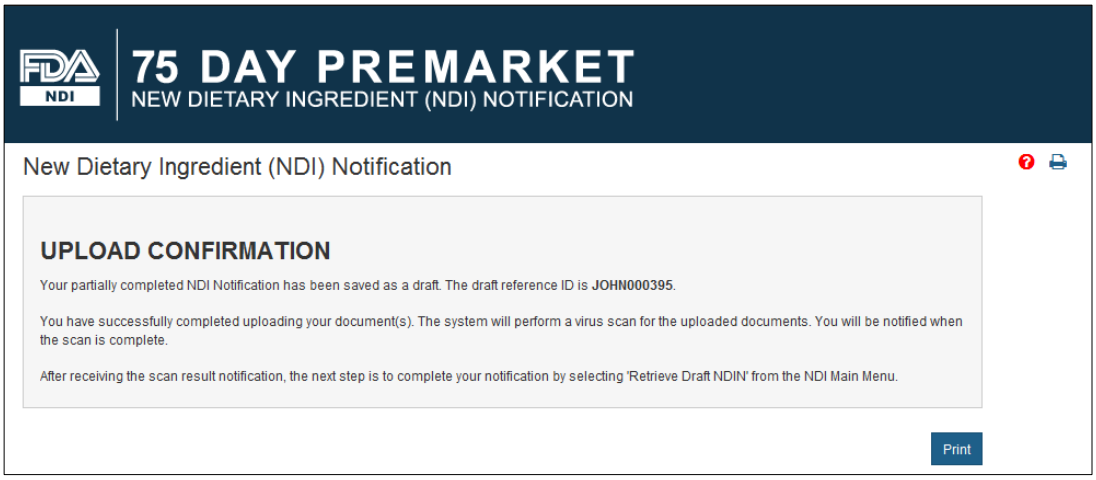


Figure 13:



The next screen (see **Figure 14** below) confirms that the attachments have been uploaded, and explains the next step that is required to complete the notification. After you have uploaded the attachments to your notification, close this screen and wait for an e-mail (that will be sent to the designated Point of Contact at the beginning of the notification submission process) stating that your documents have been scanned and processed.

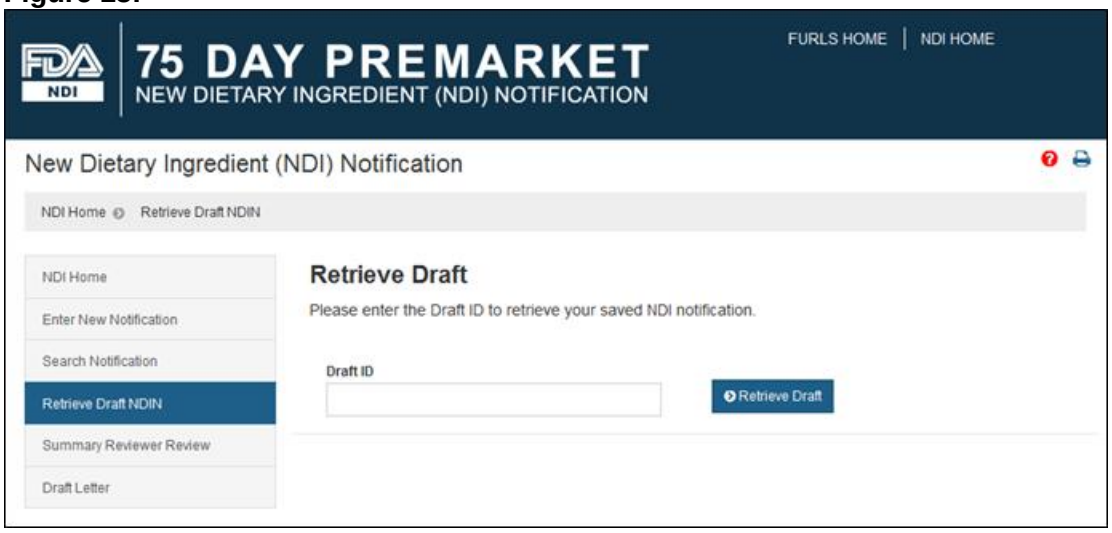
Figure 14:



STEP 6

Once the documents that you uploaded have been processed (i.e., you received the confirmatory email) you will go back to the NDI Notification Home Page and select "Retrieve Draft NDI" from the menu on the left hand side of the page (see **Figure 15** below). Type in your reference number supplied in the last page (**Figure 14**) and you will be taken to the preview page.

Figure 15:



Preview Page

The NDIN review page is provided is shown in **Figure 16** below. You will still be able to edit your notification in future pages. To continue, click on the "Complete Draft" button in the lower right corner of the screen.

Figure 16:

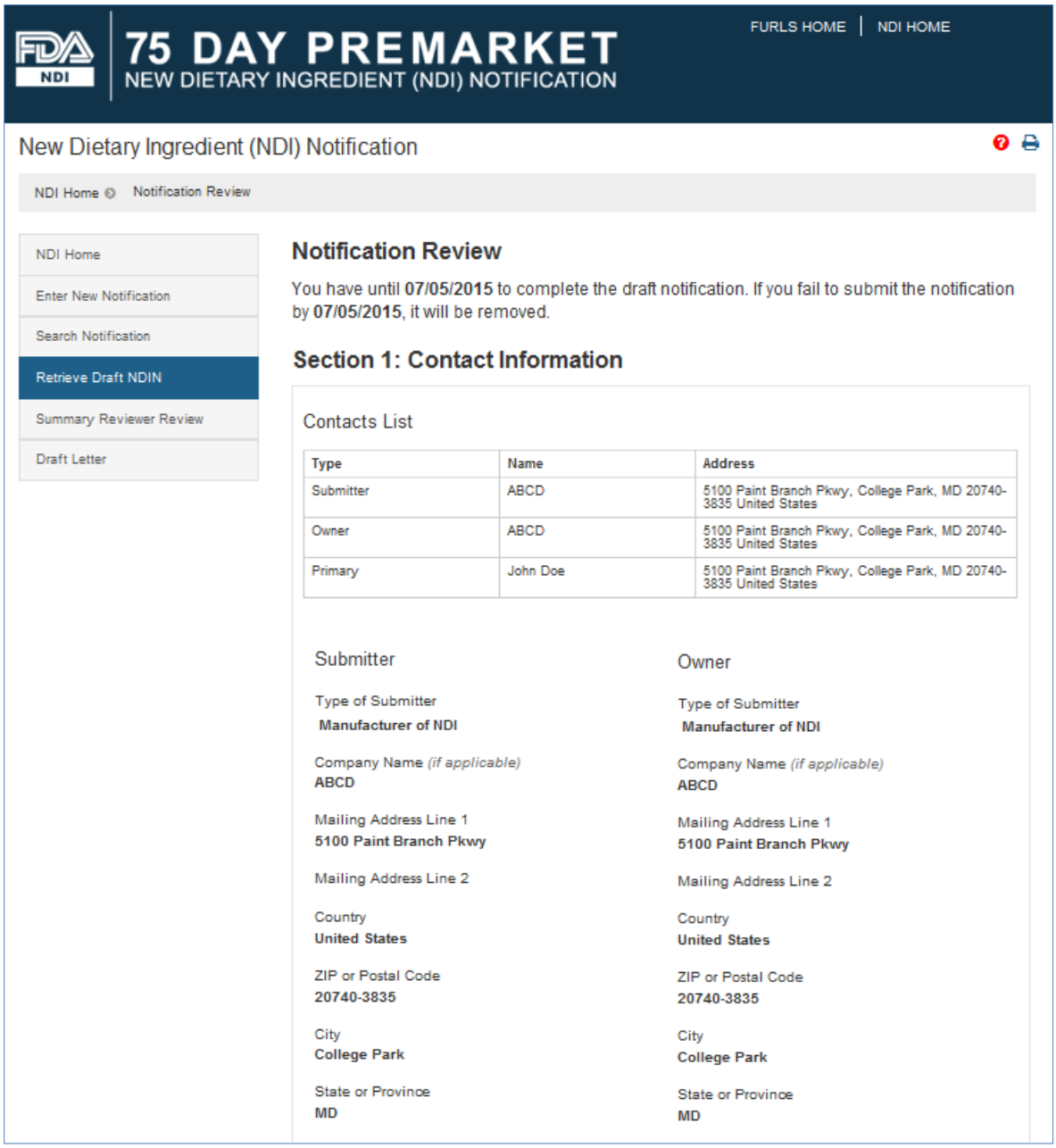
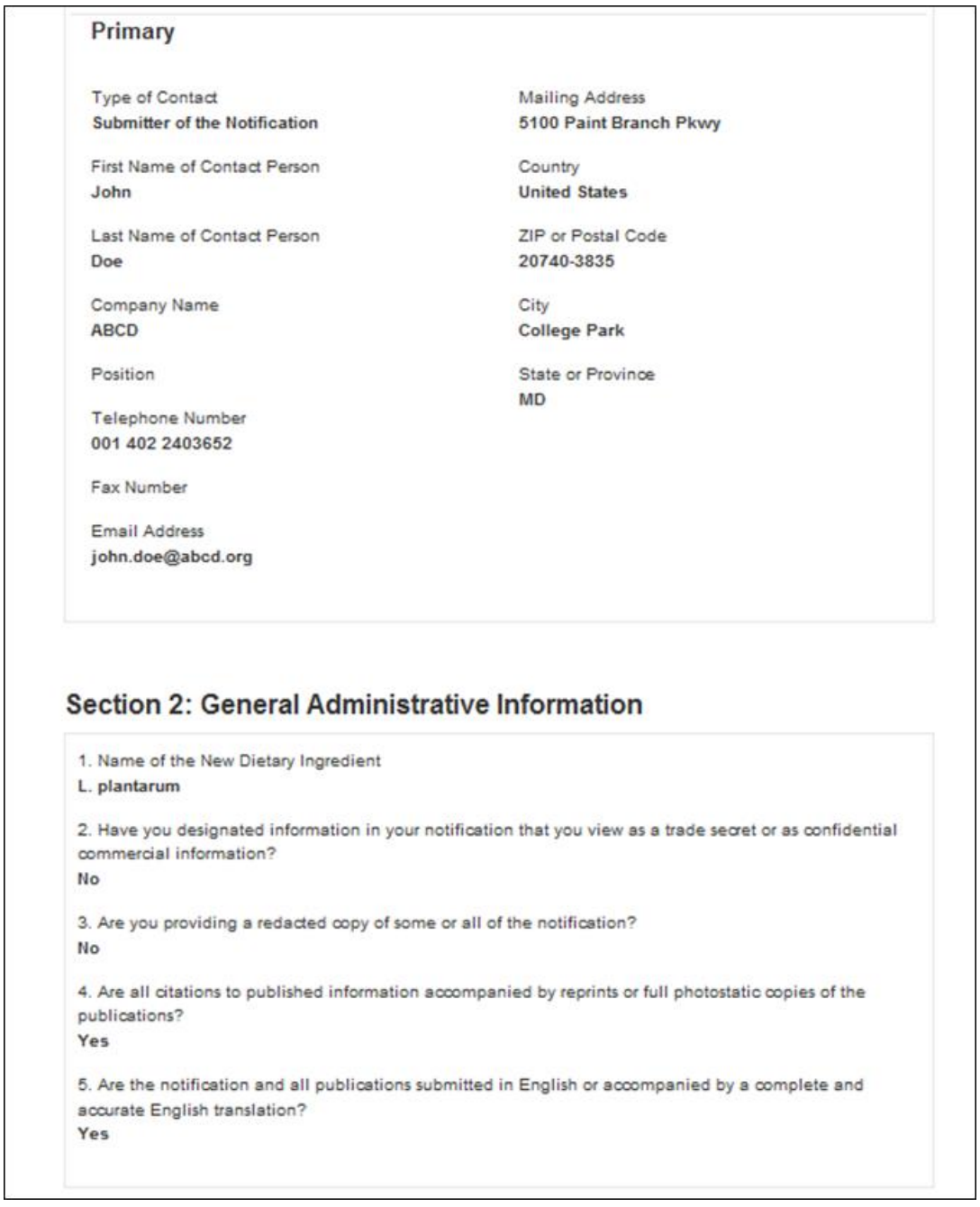

FDA
NDI
75 DAY PREMARKET
NEW DIETARY INGREDIENT (NDI) NOTIFICATION
FURLS HOME | NDI HOME
New Dietary Ingredient (NDI) Notification
NDI Home
Notification Review
NDI Home
Enter New Notification
Search Notification
Retrieve Draft NDIN
Summary Reviewer Review
Draft Letter
Notification Review
You have until 07/05/2015 to complete the draft notification. If you fail to submit the notification by 07/05/2015, it will be removed.
Section 1: Contact Information
Contacts List
Type
Name
Address
Submitter
ABCD
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Owner
ABCD
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Primary
John Doe
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Submitter
Type of Submitter
Manufacturer of NDI
Company Name (if applicable)
ABCD
Mailing Address Line 1
5100 Paint Branch Pkwy
Mailing Address Line 2
Country
United States
ZIP or Postal Code
20740-3835
City
College Park
State or Province
MD
Owner
Type of Submitter
Manufacturer of NDI
Company Name (if applicable)
ABCD
Mailing Address Line 1
5100 Paint Branch Pkwy
Mailing Address Line 2
Country
United States
ZIP or Postal Code
20740-3835
City
College Park
State or Province
MD

Figure 16 Cont:



Primary

Type of Contact
Submitter of the Notification

First Name of Contact Person
John

Last Name of Contact Person
Doe

Company Name
ABCD

Position

Telephone Number
001 402 2403652

Fax Number

Email Address
john.doe@abcd.org

Mailing Address
5100 Paint Branch Pkwy

Country
United States

ZIP or Postal Code
20740-3835

City
College Park

State or Province
MD

Section 2: General Administrative Information

1. Name of the New Dietary Ingredient
L. plantarum

2. Have you designated information in your notification that you view as a trade secret or as confidential commercial information?
No

3. Are you providing a redacted copy of some or all of the notification?
No

4. Are all citations to published information accompanied by reprints or full photostatic copies of the publications?
Yes

5. Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation?
Yes

Figure 16 Cont:

Section 3: Description of NDI and Dietary Supplement Containing the NDI

1. New Dietary Ingredient Type

Dietary substance for use by man to supplement the diet by increasing the total dietary intake

2. Name of the new dietary ingredient and related information
Maximum level of new dietary ingredient in each serving of dietary supplement (include units)

L. plantarum

NDI Name
L. plantarum

Latin Binomial Name (LBN)

Author of LBN

Synonyms and Trade Name

Plant Part and Strain

3. Dietary supplement serving form

Capsule

4. Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement. If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., greater than 99% purity, 50:1 dry leaf extract, or fermentation product)).
1000 cfu

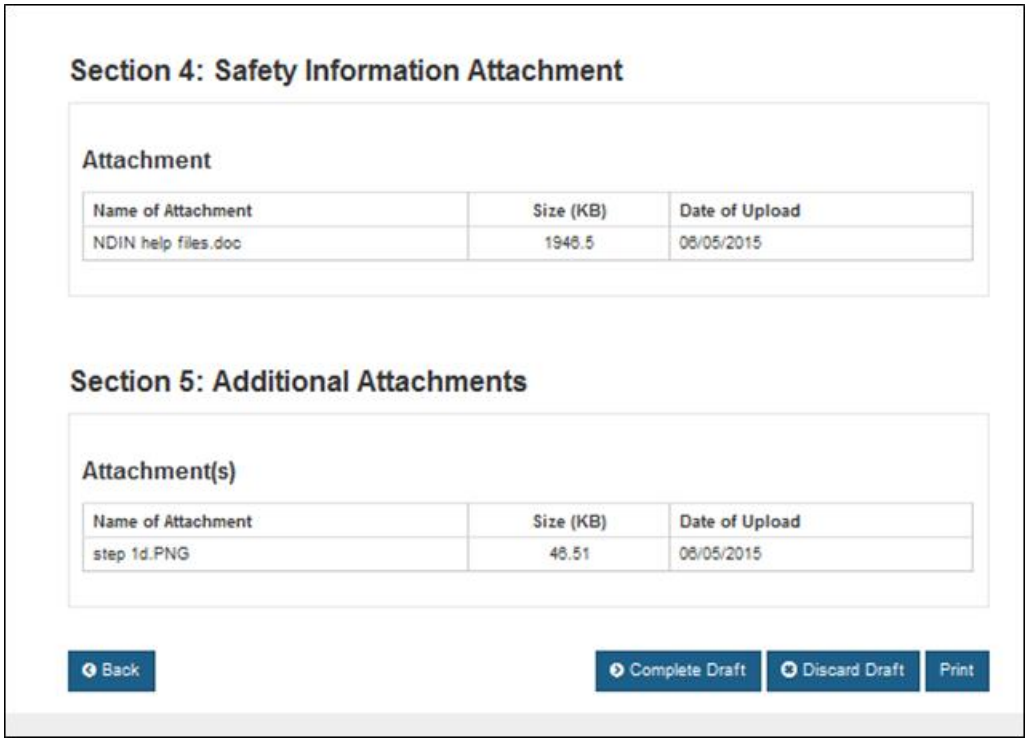
5. Conditions of Use of the Dietary Supplement

5a. Serving instructions (e.g., "take with food", "take before bed", "dissolve in a glass of water", etc).
take with food

5b. Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level
one capsule

5c. Target populations / excluded populations / other restrictions
adults

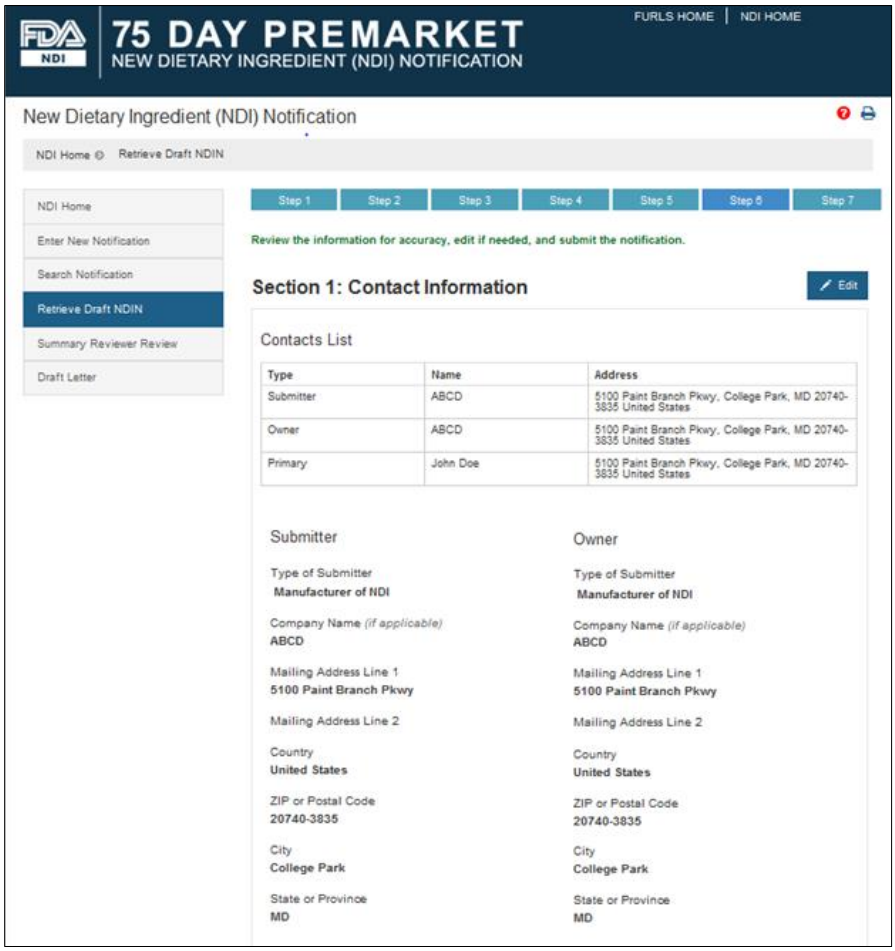
Figure 16 Cont:



The following pages will repeat Steps 1-5 again and you will review the figures shown above. This will allow you to make any changes to your notification and click “Next” in the bottom right corner of the screen to continue through the submission process until you get to Step 6.

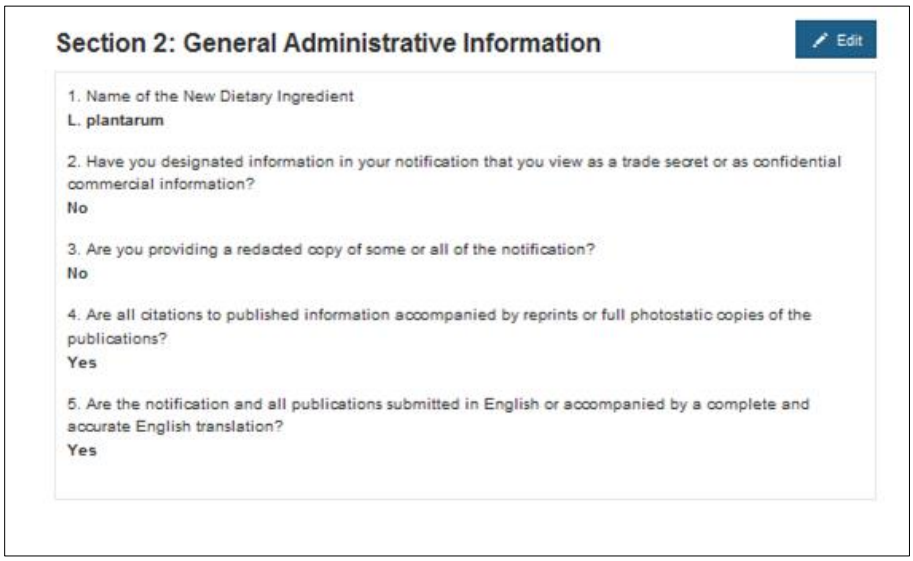
The NDIN review page is provided next (see Figure 17 below). Please review the information in your notification and correct any errors by clicking on the “edit” button at the top left side of each section.

Figure 17:


FDA NDI
75 DAY PREMARKET
NEW DIETARY INGREDIENT (NDI) NOTIFICATION
FURLS HOME | NDI HOME
New Dietary Ingredient (NDI) Notification
NDI Home
Retrieve Draft NDIN
NDI Home
Enter New Notification
Search Notification
Retrieve Draft NDIN
Summary Reviewer Review
Draft Letter
Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7
Review the information for accuracy, edit if needed, and submit the notification.
Section 1: Contact Information
Edit
Contacts List
Type
Name
Address
Submitter
ABCD
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Owner
ABCD
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Primary
John Doe
5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Submitter
Type of Submitter
Manufacturer of NDI
Company Name (if applicable)
ABCD
Mailing Address Line 1
5100 Paint Branch Pkwy
Mailing Address Line 2
Country
United States
ZIP or Postal Code
20740-3835
City
College Park
State or Province
MD
Owner
Type of Submitter
Manufacturer of NDI
Company Name (if applicable)
ABCD
Mailing Address Line 1
5100 Paint Branch Pkwy
Mailing Address Line 2
Country
United States
ZIP or Postal Code
20740-3835
City
College Park
State or Province
MD


Primary
Type of Contact
Submitter of the Notification
First Name of Contact Person
John
Last Name of Contact Person
Doe
Company Name
ABCD
Position
Telephone Number
001 402 2403652
Fax Number
Email Address
john.doe@abcd.org
Mailing Address
5100 Paint Branch Pkwy
Country
United States
ZIP or Postal Code
20740-3835
City
College Park
State or Province
MD

Figure 17 Cont:



Section 2: General Administrative Information

Edit

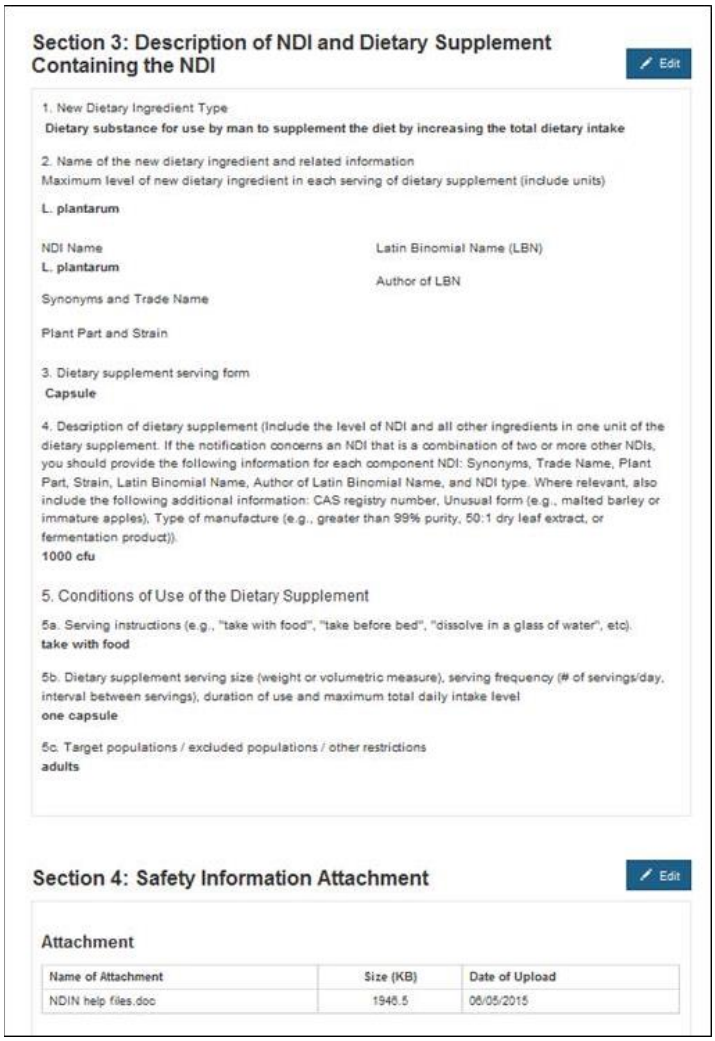
1. Name of the New Dietary Ingredient
L. plantarum

2. Have you designated information in your notification that you view as a trade secret or as confidential commercial information?
No

3. Are you providing a redacted copy of some or all of the notification?
No

4. Are all citations to published information accompanied by reprints or full photostatic copies of the publications?
Yes

5. Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation?
Yes



Section 3: Description of NDI and Dietary Supplement Containing the NDI

Edit

1. New Dietary Ingredient Type
Dietary substance for use by man to supplement the diet by increasing the total dietary intake

2. Name of the new dietary ingredient and related information
Maximum level of new dietary ingredient in each serving of dietary supplement (include units)
L. plantarum

NDI Name
L. plantarum

Latin Binomial Name (LBN)

Author of LBN

Synonyms and Trade Name

Plant Part and Strain

3. Dietary supplement serving form
Capsule

4. Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement. If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., greater than 99% purity, 50:1 dry leaf extract, or fermentation product)).
1000 cfu

5. Conditions of Use of the Dietary Supplement

5a. Serving instructions (e.g., "take with food", "take before bed", "dissolve in a glass of water", etc).
take with food

5b. Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level
one capsule

5c. Target populations / excluded populations / other restrictions
adults

Section 4: Safety Information Attachment

Edit

Attachment

Name of Attachment	Size (KB)	Date of Upload
NDIN help files.doc	1946.5	06/05/2015

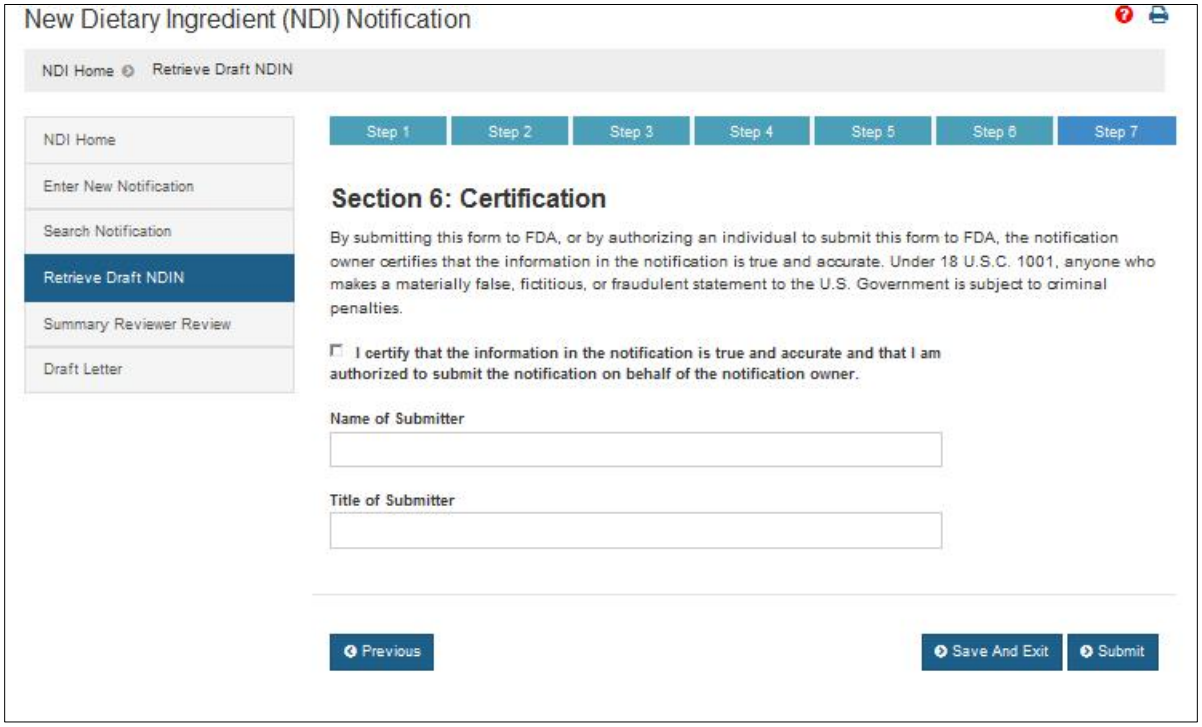
Figure 17 Cont:

STEP 7

Section 6: Certification

All information must be completed for Section 6 (see **Figure 18** below) in order to submit your notification and receive a confirmation of receipt from FDA.

Figure 18:



After you submit the notification, you will be directed to a confirmation screen similar to **Figure 19** below.

Figure 19: